

Pharmacy & the Future: A Compliant, Safe and Sustainable Approach to Managing Pharmaceutical Waste

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Pharmaceutical Waste Management

Regulations & References

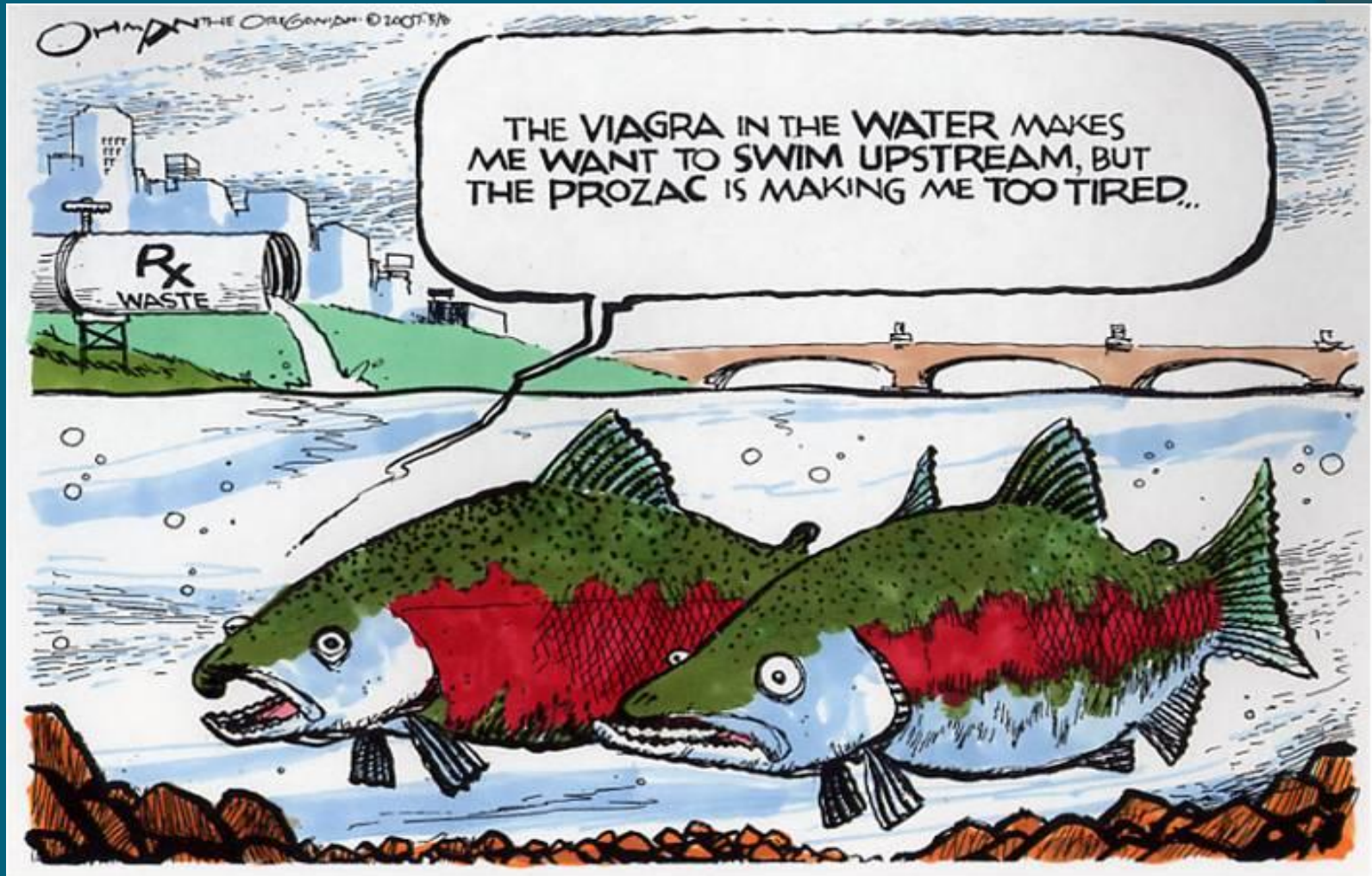
The information provided in this presentation is based on the referenced Code of Federal Regulations and State regulations. This data is presented only as a reference. For complete requirements or legal counsel on hazardous waste regulations and interpretations, generators should consult their legal department, the applicable Code of Federal Regulations and applicable State regulatory agencies.

Pharmaceutical Waste Management

Disclosure Declaration

As a Consultant to Stericycle, I have a vested interest in and affiliation with a corporate organization offering financial support or grant monies for this continuing education activity and, a business interest in pharmaceutical waste management services.

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Understanding 3 Key Issues when looking at Pharmaceutical Waste

- *Is your facility properly segregating and disposing of pharmaceutical waste?*
- *Does your facility manage such the disposal process internally or use outside resources?*
- *Do you know what is considered “pharmaceutical waste”?*

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Presentation Objectives

1. Outline environmental and human health concerns regarding pharmaceutical waste in water supply
2. Explain regulatory requirements for pharmaceutical waste disposal and updates on changes and proposed changes
3. List/define various classes of pharmaceutical waste streams and illustrate examples of each
4. Review service requirements for a compliant pharmaceutical waste management program and its hospital-wide impact
5. Explain how to implement and manage a sustainable program for pharmaceutical waste disposal, including multiple hospital departments

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RX Waste Disposal – Who Is Involved?

- Environmental Protection Agency (EPA-RCRA & CWA)
- Department of Transportation (DOT)
- Drug Enforcement Agency (DEA)
- Occupational Safety & Health (OSHA)
- California EPA & CA Department of Public Health
- Publicly Owned Treatment Works (POTW)
- The Joint Commission (TJC)

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A Growing Concern

USGS (US Geological Survey) Water Survey (1999-2000)

- Organic Wastewater Contaminants (OWCs) in 80% of streams tested
- 33% of OWCs detected were pharmaceuticals.

Media Coverage

- 3/9/08 USA Today - “AP Probe finds drugs in drinking water”
- 9/15/08 USA Today/AP report - “Hospitals dumping drugs into water”
- 5/24/10 Modern Healthcare – “Drugged”

EPA Regulatory Activity

- Notice of Violations and warnings
- Increasing regulatory scrutiny country wide. Local Agencies getting more involved
- Fines in excess of \$500,000
(VA Eastern Kansas Health System, Aug. 2009, \$533,570)

The Joint Commission (TJC)

- Medication Management, Environment of Care, and Leadership standards

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EPA Fine

_____ Center Corrects Federal Environmental Violations (SAN FRANCISCO -9/9/2008)

The U.S. Environmental Protection Agency today announced that the _____ Care System has agreed to pay a **\$32,544** penalty for violations of federal environmental regulations at its Palo Alto, Calif., teaching hospital.

The _____ **violated five requirements of the federal Resource Conservation and Recovery Act,** which governs the storage and handling of hazardous materials.

"It's especially important that institutions, especially hospitals, follow hazardous waste regulations in order to prevent human exposures and environmental damage," said Jeff Scott, director of the Waste Division for the EPA's Pacific Southwest region.

The environmental violations were discovered during a routine inspection conducted jointly by the U.S. EPA and Santa Clara's Department of Environmental Health. The inspection was to determine whether the facility was in compliance with federal and state regulations concerning the proper management of hazardous waste.

The facility was inspected on March 21, 2007 and charged with the following counts:

- **Storage of hazardous waste without a permit,**
- **Open containers,**
- **Inadequate facility maintenance,**
- **Ignitable waste within 50' of property line,**
- **Failure to make a hazardous waste determination.**

Shortly after the EPA's inspection, the hospital addressed all of its violations -- coming into compliance with RCRA regulations. To ensure they remain compliant, the _____ has instituted a new tracking system for managing pharmaceutical waste.

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Common EPA Inspection Issues

- ⦿ Hazardous waste determinations not done or incorrect
- ⦿ Labeling of hazardous waste not done or incorrect
- ⦿ Throwing HW down the drain
- ⦿ Improper disposal of chemotherapy drugs
- ⦿ Inadequate training for employees in HW management
- ⦿ Not conducting proper weekly inspections of HW storage
- ⦿ No or inadequate HW manifests
- ⦿ Lack of emergency contingency plan
- ⦿ Improper management of expired pharmaceuticals

“Identification and Management of Regulated Hazardous Waste” – EPA Region 2

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TJC Accreditation

- **MM.01.01.03 - Medication Management**

- The hospital safely manages high-alert and hazardous medications
- The hospital identifies, in writing, its high-alert and hazardous medications
- The hospital has a process in place that addresses how outside resources, if any, are used for the destruction of pharmaceuticals.

- **EC.02.02.01 - Environment of Care**

- The hospital manages its hazardous materials wastes risks.
- The hospital minimizes risk associated with disposing hazardous medications.

- **LD.04.01.01 - Leadership**

- The hospital complies with law and regulation.

- **EM.02.02.05 – Emergency Management**

- The organization prepares for how it will manage hazardous materials and waste.

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Understanding the Issues

- *Do you know what is considered “pharmaceutical waste”?*
- *Is pharmaceutical waste all either P- or U-listed?*

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The Basics of Pharmaceutical Waste

Pharmaceutical Waste consists of any Pharmaceutical Product that is:

- No longer used for their intended purpose
- Designated for discard
- Not returnable for credit



Pharmaceutical Waste

- Partial vials (safety caps removed)
- Un-dispensed,
- Pre-instilled IV's
- Hospital repacks
- Pre-filled syringes
- Partial syringes
- Discontinued meds
- Un-administered meds
- Patient prescriptions
- Physician RX samples



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CURRENT WASTE STREAMS

Red Bags

Sharps

Trace Chemo

Bulk Chemo

**Non-RCRA
Rx Waste**

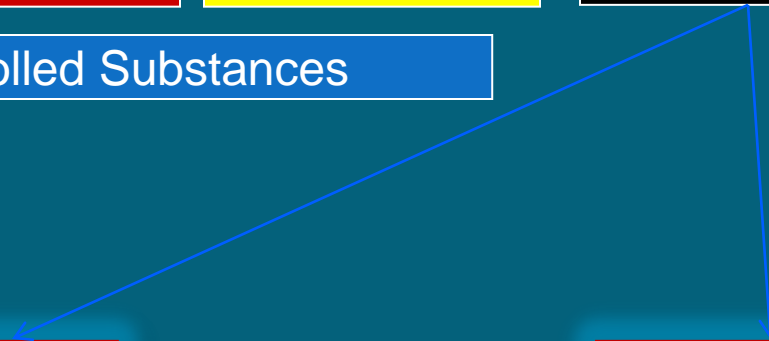
Controlled Substances

**Compatible
Hazardous
Rx Waste**

4%

**Incompatible
Hazardous
Rx Waste**

1%



California Hazardous Pharmaceutical Waste

- ⦿ Prescription or over-the-counter human or veterinary drug
- ⦿ Does NOT include any pharmaceutical regulated pursuant to:
 - RCRA
 - The Radiation Control Law
- ⦿ Senator Wright's clarification – those pharmaceuticals that were otherwise regulated as hazardous in California

Unregulated Pharmaceutical Wastes

- Pharmaceutical wastes not regulated by RCRA and California Hazardous – MWMA, are unregulated
- HOWEVER, the POTW and Landfills may not accept them – an orphan waste
- Can handle as a California Hazardous pharmaceutical waste and send to a medical waste incinerator

Catagories of RCRA Hazardous Waste

- Characteristic Waste - 4 characteristics
Ignitability, Corrosively, Reactivity, Toxicity
- Listed Wastes
 - **P – Listed**
 - **U – Listed (chemotherapy drugs)**

Other categories of Hazardous Waste

- Compatible vs. Incompatible Pharmaceutical Waste
 - Drugs that can (Compatible) and **CANNOT (Incompatible)** be placed in the same container without danger of a chemical reaction

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Hospital RX Formulary Analysis

<u>NDC's</u>	<u>% NDC's</u>	
2,615	100.0%	Total Characterized
196	7.5%	RCRA Hazardous
2,419	92.5%	Non-Hazardous

P&U Listed vs Characteristic

196	100.0%	Total RCRA Hazardous
146	74.5%	Characteristic Hazardous
50	25.5%	Total P&U Listed Hazardous
		30 (15.3%) P-Listed Hazardous
		20 (10.2%) U-Listed Hazardous

Compatibility

182	93.0%	Hazardous Compatible
14	7.0%	Hazardous Incompatible

RCRA Characteristic Hazardous Waste

- **Ignitability** - Aqueous Solution containing 24% alcohol or more by volume & flash point < 140° F., D001 waste.
- **Corrosivity** - An aqueous solution having a pH ≤ 2 or ≥ 12.5, D002 waste.
- **Reactivity** – Must meet eight separate criteria identifying certain explosive and water reactive wastes. D003 waste.

NOTE: Nitroglycerin formulations are excluded federally from the P081 listing as non-reactive as of August 14, 2001 under FR: May 16, 2001. States must have adopted the exclusion.

- **Toxicity** - Approximately 40 chemicals which meet specific leaching concentrations. Examples of toxic pharmaceuticals at indicated maximum concentrations: Arsenic (5.0 mg/L), Barium (100.0 mg/L), Mercury (0.2 mg/L), Cadmium 1.0 mg/L, Chloroform (6.0 mg/L), Selenium (1.0 mg/L), Chromium 5.0 mg/L, Silver (5.0 mg/L), m-Cresol (200.0 mg/L)

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Characteristically Hazardous Waste



Characteristic Hazardous



- Lantus
- Humalog
- Humulin N
- Humulin R
- Centrum Silver
- Flovent
- Taxol
- Atrovent



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Examples of Listed RX Waste

P – Listed

- Arsenic trioxide
- Epinephrine (Base)
- Nicotine
- Physostigmine
- Warfarin



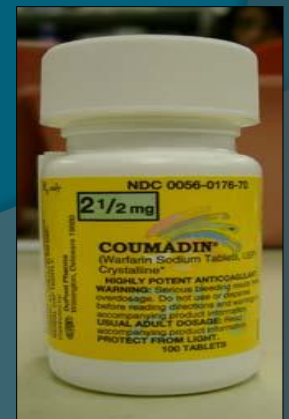
U – Listed

- Chemotherapy drugs
- Cytoxan
- Chloroform
- Mercury
- Mitomycin
- Phenol
- Saccharin
- Selenium Sulfide

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Waste Characterization

- Identify all Listed and Characteristic RCRA Hazardous RX
- Characterization must be based on both active **AND** inactive or preservative ingredients
- Determine **both** EPA/RCRA and DOT hazardous material class at NDC level
- Consider industry best practices (NIOSH, ASHP & OSHA) re: identifying non-RCRA chemo & environmentally dangerous drugs
- **NOTE:** MSDS sheets do not always provide information on inactive/preservative ingredients



U.S. DOT Regulations

DOT regulations (49 CFR):

1. Classification, description, and packaging
2. Proper marking and labeling
3. Segregation into proper streams
4. Training
5. Security

Hazmat Implementation Act:

- Fine section recently rewritten to raise fines
- Currently fines average \$30,000 per violation and range up to \$100,000

U.S. DOT HM229

- If a generator ships hazmat without proper documentation the carrier must report it or the carrier can be prosecuted with the shipper.

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Training

RCRA Training

- Employees who are involved with or occupationally exposed to hazardous waste must be trained.
- Training must be completed within 6 months
- Annual retraining
- Record retention requirement

Hazard Communication Training

- Employees who are involved with or occupationally exposed to hazardous chemicals must be trained in accordance with 29 CFR 1910.200
- Training must be completed at time of initial assignment to the job

DOT Training

- Employees who are involved with or occupationally exposed to hazardous materials must be trained in accordance with 49 CFR Subpart H 265 (172.702 & 172.704)
- Training must be completed within 90 days
- Retraining required every three years
- Record retention requirement

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Pharmaceutical Waste Management Service & Logistics

Satellite Accumulation

- ◎ Identify satellite accumulation areas
- ◎ EPA requirements for satellite accumulation:
 - At or near point of generation
 - Under generator's control
- ◎ Locations
 - Pharmacy
 - Patient-care areas
 - ✓ Med rooms
 - ✓ Soiled utility rooms
 - ✓ Nurses stations

Transportation & Disposal

- ⦿ Industry “best practice” is to incinerate all Rx Waste (ASHP, Practice Greenhealth, EPA Office of Water)
- ⦿ Non-RCRA can be over-classified and incinerated at a regulated medical waste incineration facility
- ⦿ RCRA hazardous waste must be transported by a licensed hazardous waste hauler
- ⦿ RCRA hazardous waste must be incinerated at an EPA permitted hazardous waste facility
- ⦿ Check permit limitations of hazardous waste incinerators

Staff Education

- Train
 - EVS
 - Pharmacy
 - Nursing/Clinicians
- Training Topics
 - Regulatory requirements
 - Containers
 - Waste segregation
 - Transportation & Disposal

On-going Support

- Characterization of new additions to formulary
- Ongoing support - program audit and training
- Annual audit to ensure compliance
 - Manifests
 - Training Records
 - Accumulation Area weekly inspections
 - Proper segregation
- Annual EPA-RCRA training

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Developing a Plan for Pharmaceutical Waste Management

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Getting Started

1. Understand the need for a pharmaceutical waste program based on regulatory involvement and environmental concerns.
2. Evaluate how pharmaceutical waste is currently being handled in comparison to federal and state regulations.
3. Identify a group of leaders in your facility that have a passion for the environment who will champion multi-departmental cooperation and administration support.
4. Have the CEO's blessing and authorization.

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Getting Started

Departments with champions that help advocate for compliant and environmentally responsible pharmaceutical waste disposal:

Pharmacy

Environmental Services

Infection Control

Quality/Accreditation

Purchasing

Risk Management

Nursing

Nursing Education

Facilities Management

Safety

Public Relations

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Selection and Assessment

1. Understand the scope of the issue by learning which pharmaceuticals are hazardous
2. Identifying program options
 - In-house program or using an outside vendor or consultant?
3. Compare potential cost and risks associated with each program option
 - In-house program (*cost, availability of hospital personnel*)
 - Computer system (*cost, compliance concerns with commingling of compatible and non-compatible waste*)
 - Hazardous waste consultant/broker (*cost, compliance concerns with regards to commingling, knowledge and resources*)
 - Multi-waste stream company (*comprehensive, turnkey program*)

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Selection and Assessment

What should a Pharmaceutical Waste Program include?

- *Characterization of entire RX formulary per EPA & DOT regulations*
- *Education for staff (pharmacy, nursing, environmental services)*
- *Container system for waste collection that includes segregation per hazardous class (preferably with reusable containers to minimize waste volumes and reduce costs)*
- *Incineration of all pharmaceutical waste in appropriately permitted facilities to assure compliance and control costs*
- *Ongoing waste characterization of new RX products*
- *Ongoing support (operations, regulatory updates, continuing staff training)*
- *Single point of contact*

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Program Implementation

1. Identification and Information Systems

- Formulary characterization
- Employ RX waste codes on pharmacy labels and in dispensing cabinets (Pyxis, Omnicell, etc.) to simplify waste identification and segregation
- Select locations for pharmaceutical waste containers in pharmacies and patient care areas

2. Staff Training

- Pharmacy
- Nursing
- Environmental Services

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Waste Collection Process

1. Installation of pharmaceutical waste collection containers done immediately after staff training
2. Reinforcing proper and compliant pharmaceutical waste disposal practices with posters and “cheat sheets”
3. Identify how to handle:
 - *Controlled Substances*
 - *IV solutions that can still go down the drain*
 - *Partial IV's with instilled medications*
 - *RCRA pharmaceuticals*
 - *Compatible*
 - *Non-compatible – special marked containers or return to pharmacy for handling*
 - *California hazardous – over classify or handle as medical waste pharmaceutical*
4. Container collection/exchange process

HIPAA Label Solutions

- ⦿ Concern that patient information (potential HIPAA violation) may be on the IV bags that have contained pharmaceuticals
- ⦿ Can resolve this issue with:
 - Identi-Hide™ Label
 - Patient Identification Self-Shred Labels

Legislative Update

- AB 1442 (Chapter 689 Statutes of 2012)
of the Medical Waste Management Act

- Redefines *pharmaceutical waste*

- Defines *common carrier*

- Updates requirements for including common carrier in MW Management Plans

- Allows shipping of pharmaceutical waste by common carrier with certain requirements

Rulemaking Update

- ⦿ Department of Justice Proposed Rulemaking regarding controlled substances
- ⦿ http://www.ofr.gov/OFRUpload/OFRData/2012-30699_PI.pdf
- ⦿ Comment period is still open

Summary

Pharmaceutical Waste Management

1. Regulatory and TJC compliance
2. Environmental Stewardship
3. Understanding what pharmaceutical waste is and how to handle it
4. Implementing a sustainable program
5. New and pending law and rule changes

Questions?

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Thank You